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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/888,264

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Sean H. Adams

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7590

03/26/2003

Paul E. Rauch, Ph.D.
c/o Brinks Hofer Gilson & Lione
P.O. Box 10395
Chicago, IL 60610

EXAMINER

ANGELL, JON E

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 03/26/2003

[Handwritten signature]

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,264

Applicant(s)

ADAMS ET AL.

Examiner

J. Eric Angell

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 27-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 27-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Action is in response to the communication filed on 11/27/02, as Paper No. 15. The amendment has been entered. Claim 1 has been amended. Claims 3-26 have been cancelled. New claims 27-37 have been added. Claims 1, 2 and 27-37 are currently pending in the application and are examined herein.
2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. For example, page 6 (line 10) of the specification contains a hyperlink. All hyperlinks must be removed from the specification.

Response to Amendment

It is acknowledged that in an interview with the attorney of record (Paul Rauch) a proposed claim amendment was discussed which would overcome the rejections set forth in the previous Office Action. Applicants have entered the proposed claim amendment, and although the amendment overcomes the 112, first and second paragraph rejections previously set forth,

upon further consideration, the amendment fails to overcome the 102 rejection for the reasons indicated herein.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 remains rejected and new claims 27, 29, 30, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Palmisano et al. (Biochem. Journal, 333:151-158, 1998).

Claim 1 is drawn to a method comprising (a) contacting a mammalian cell or tissue sample with a candidate compound; and (b) analyzing the expression of a polypeptide having at least 90% amino acid sequence identity to the polypeptide encoded by SEQ ID NO. 1 or 2 (human OGC) and having uncoupling activity within the sample. Claims 27, 29, 30, 34 and 35 depend on claim 1 and further limit the method to analyzing the expression of a polypeptide at least 95% identical to the amino acid sequence encoded by SEQ ID NO. 1 or 2.

It is noted that a method comprising contacting a mammalian cell or tissue sample with a compound and analyzing the expression of a polypeptide have 90% (or 95%) identity to the polypeptide encoded by SEQ ID NO 1 or 2 (human OGC) would meet the limitations of the claims.

Palmisano teaches a method comprising contacting a mammalian tissue sample (here, rat liver mitochondria –see p. 153, figure 1; and p. 156, figure 4) with a candidate compound (e.g.,

trypsin, TX-100, Apyrase, or ATP –see p. 153, Figure 1; or digitonin, see Figure 4) and analyzing the expression of OGC within the sample (see Figures 1 and 4). Specifically, Palmisano indicates that the OGC used in the experiments is bovine OGC (see p. 152, paragraph bridging columns 1 and 2). Looking at the amino acid sequence of bovine OGC in Genbank (Accession No. AAA30672 (gi 163434), and aligning the bovine with the human OGC (Accession No. gi 3387911) amino acid sequence, indicates that the bovine OGC and human OGC are 96% identical. Therefore, Palmisano clearly anticipates the instant claims.

3. Claims 1, 2 and 27-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Appleby et al (Eur. J. Biochem. Vol. 262, p. 108-116; May 1999).

Claim 1 is drawn to a method comprising (a) contacting a mammalian cell or tissue sample with a candidate compound; and (b) analyzing the expression of a polypeptide having at least 90% amino acid sequence identity to the polypeptide encoded by SEQ ID NO. 1 or 2 (human OGC) and having uncoupling activity within the sample.

Claim 2 further limits the method of claim 1 by requiring an additional step of measuring mitochondrial membrane potential in the cell. Claims 27-37 depend on claim 1 and further limit the method to analyzing the expression of a polypeptide at least 95% identical to the amino acid sequence encoded by SEQ ID NO. 1 or 2 and some claims (28, 31-33, 36 and 37) require that the mammalian cell/tissue be a human cell/tissue.

Appleby teaches a method for identifying factors involved in mitochondrial membrane potential wherein the factors are not encoded by mitochondrial DNA. The method taught by Appleby comprises treating human cells with compounds such as azide and oligomycin, isolating

the mitochondria from the treated cell, subfractionating the isolated mitochondria into membrane and matrix fractions and then analyzing all of the mitochondrial associated proteins by blue native polyacrylamide electrophoresis (BN/PAGE). (See abstract; p. 109, first column; p. 110, first column; and p. 114, Figure 6a). It is noted that human OGC was known to be a polypeptide localized to mitochondria. Therefore, treating the human cells with azide or oligomycin isolating and fractionating the mitochondria and analyzing the proteins localized to the mitochondria by BN/PAGE would analyze the expression of all of the mitochondrial proteins not encoded by mitochondrial DNA, including human OGC. Therefore, Appleby anticipates the claimed invention.

Response to Arguments

4. Applicant's arguments filed 11-27-02 have been fully considered but they are not persuasive.
5. Applicants only indicate that the rejections have been obviated by the amendment.
6. This is not considered persuasive with respect to the rejection of claims under 35 USC 102 (b) for the reasons set forth above.
7. The rejections of claims under 35 USC 112, first and second paragraph are obviated by the amendment.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell, Ph.D.
March 21, 2003



JEFFREY FREDMAN
PRIMARY EXAMINER